



# THE ASSAM GAZETTE

অসাধাৰণ

EXTRAORDINARY

প্ৰাপ্ত কৰ্তৃত্বৰ দ্বাৰা প্ৰকাশিত

PUBLISHED BY THE AUTHORITY

---

নং 265 দিশপুৰ, মঙ্গলবাৰ, 6 মে', 2025, 16 ব'হাগ, 1947 (শক)

No. 265 Dispur, Tuesday, 6th May, 2025, 16th Vaisakha, 1947 (S. E.)

---

GOVERNMENT OF ASSAM

ORDERS BY THE GOVERNOR

INDUSTRIES, COMMERCE AND PUBLIC ENTERPRISE DEPARTMENT

**NOTIFICATION**

The 26th April, 2025

**No.ECF. 612666/68.-** The Governor of Assam is pleased to notify "**Assam Pharmaceutical and Medical Device Policy, 2025**". The Policy will come into effect from the date of publication in the official Gazette for a period of 5 (five) years.

Short title and commencement	<p><b>1. 1.1</b> This policy may be called the Assam Pharmaceutical and Medical Device Policy, 2025.</p> <p><b>1.2</b> It shall come into force on the date of their publication in the Official Gazette.</p>
<b>Need for Pharmaceutical and Medical Device Policy for Assam</b>	<p><b>2.</b> Assam is emerging as a significant state in the pharmaceutical sector, with top companies like Sun Pharma, Lupin, Natco and Ajanta Pharma establishing a strong presence in the state. The recent inauguration of Chemex Global's pharmaceutical Active Pharmaceutical Ingredient manufacturing facility in Guwahati underscores Assam's growing potential. The state's strategic location and improving infrastructure offer immense logistical advantages, supporting the efficient distribution of pharmaceutical products. To fully harness this potential, a dedicated Pharmaceutical and Medical Device Policy 2025 is essential. This policy should focus on enhancing distribution networks, supporting local manufacturing and establishing a robust regulatory framework to ensure drug safety and efficacy. Economic incentives, such as subsidies and public-private partnerships, can stimulate industry growth, create jobs and attract investments. Additionally, initiatives to improve drug affordability and accessibility, along with public awareness campaigns on the rational use of medicines, are crucial. A comprehensive policy shall drive economic growth, improve healthcare access and ensure the well-being of Assam's population.</p>
<b>Vision, Mission and Target</b>	<p><b>3. 3.1 Vision</b></p> <p>To establish Assam as a key center for pharmaceutical manufacturing and innovation, guaranteeing access to high-quality, affordable medicines, while driving economic growth and enhancing healthcare outcomes for all residents.</p> <p><b>3.2 Mission</b></p> <p><b>(a) Promote Local Manufacturing:</b></p> <p>Encourage the establishment and expansion of pharmaceutical manufacturing units in Assam through incentives, subsidies and technical support.</p> <p><b>(b) Enhance Accessibility and Affordability:</b></p> <p>Implement mechanisms to ensure the widespread availability and affordability of essential medicines, particularly in remote and underserved areas.</p> <p><b>(c) Foster Innovation and Research:</b></p> <p>Support pharmaceutical research and development through public-private partnerships, facilitating a culture of innovation and technological advancement.</p> <p><b>(d) Economic Growth and Employment:</b></p> <p>Drive economic growth by attracting investments, creating jobs and supporting the development of a skilled workforce in the pharmaceutical sector.</p>

### 3.3 Objectives

(a) **Regulatory Excellence:**

Create a regulatory body within the state to oversee drug quality and safety, ensuring compliance with national and international standards.

(b) **Incentive Programs:**

Develop and implement financial incentive programs to attract pharmaceutical companies to Assam.

(c) **Support MSMEs:**

Support Micro, Small and Medium Enterprises through technology enhancement to make the Indian pharmaceutical industry more self-reliant and globally competitive.

(d) **Skill Development:**

Launch training programs in collaboration with academic institutions to build a skilled workforce in pharmaceutical manufacturing and research.

(e) **Research and Development Support:**

Provide funding and support for research and development projects, encouraging innovation in drug discovery and production.

(f) **Public-Private Partnerships:**

Foster collaboration between the government, private sector and academia to drive advancements in the pharmaceutical industry.

(g) **Environmental Sustainability:**

Promote environmentally sustainable practices in pharmaceutical manufacturing and waste management.

### 3.4 Scope

(a) **Investment Attraction:**

Facilitate and attract investors in the Pharmaceutical and Medical Devices sector

(b) **Job Creation:**

Aim to create local employment through the policy

(c) **Research and Innovation:**

Facilitate the development of new pharmaceutical research projects and collaborations with academic and research institutions in conformity with the existing central/state policy.

(d) **Regulatory Compliance:**

Achieve 100% compliance with national and international drug safety and quality standards

**Definitions****4. 4.1 MSME Unit:**

Industrial unit as defined under Micro, Small and Medium Enterprises Development Act, 2006.

**4.2 Large Unit:**

Industrial unit that exceeds the defined criteria for Micro, Small and Medium Enterprises Development Act, 2006.

**4.3 Mega Unit:**

Industrial unit as defined under existing Industrial and Investment Policy of Assam 2019.

**4.4 New Unit** means a unit, which has commenced commercial production or operation in the state of Assam during the validity period of the Assam Pharmaceutical and Medical Device Policy, 2025. A new unit shall be required to fulfil the following conditions, namely:—

- (i) It is not formed by splitting up or reconstruction of a business already in existence.
- (ii) New Industrial unit must have a new GSTIN and unit cannot use a GSTIN of any existing unit.

**4.5 Pharma and Medical Device Park:**

Private parks developed over at least 15 acres land for Pharmaceuticals and Medical device industries.

**4.6 Research and Development:**

Include Research and Development shall work done to develop new drug, new formulation, novel technology of production, novel drug delivery system, development of formulation, development of new medical device etc.

**4.7 Active Pharmaceutical Ingredient (API):**

Any substance or mixture of substances intended to be used in the manufacture of a drug (medicinal) product and that, when used in the production of a drug, becomes an active ingredient of the drug product. Such substances are intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment or prevention of disease or to affect the structure or function of the body.

**4.8 Drug Intermediate (DI):**

A material produced during intermediate steps in the synthesis of an Active Pharmaceutical Ingredient that must undergo further molecular change or processing before it becomes an Active Pharmaceutical Ingredient.

**4.9 Key Starting Material (KSM):**

A raw material, intermediate or an API that is used in the production of an API and that is incorporated as a significant structural fragment into the structure of the API. KSM can be an article of commerce, a material purchased from one or



more suppliers under contract or commercial agreement or produced in-house. KSMs are normally of defined chemical properties and structure.

**Policy  
Implementation**

**5. 5.1 Policy Period and Coverage**

The Assam Pharmaceutical and Medical Device Policy 2025 shall be valid for a period of 5 years from the date of notification of this policy in the Official Gazette. The policy shall cover the entire state of Assam, ensuring that all eligible units setting up their base within the state can avail of the benefits and incentives offered under this policy.

**5.2 Eligibility for Availing Financial Support**

**The Eligibility for availing Financial Support under this policy shall be the following, namely:—**

- (a) It must be a New unit.
- (b) An Industrial Unit in which Central or State Government or Public Sector Enterprises or any other Government bodies which has more than 50% stake/shareholding shall not be eligible.
- (c) **Employment:**  
Units shall have to employ minimum of 80% people of Assam in the Managerial Cadre and minimum 90% people of Assam in Non-Managerial Cadre.
- (d) The intending unit shall be fully compliant of all regulatory and statutory requirements, norms, guidelines prescribed under any Central or the State Acts or any Regulatory Authority or Authorities in existence.

**5.2.1 Nature of Business for eligibility:**

The company or entity should be engaged in one of the following businesses:

- (a) Manufacturing of pharmaceutical products, including generic drugs, biosimilars, vaccines, active pharmaceutical ingredients (APIs) and intermediates.
- (b) Manufacturing of Medical Devices
- (c) Private Pharmaceutical and Medical Device Parks

**5.3 Policy Promotion**

A comprehensive marketing and branding strategy shall be formulated to promote the policy at national and international forums. The Nodal Agency shall handle the following tasks, namely:—

- (a) Creating a strong brand image of the pharmaceutical sector in Assam and the policy.
- (b) Organizing and participating in national and international conferences, summits, roadshows and events to attract investors.

- (c) Utilizing print, electronic and social media platforms to raise awareness about Assam's attractiveness for the pharmaceutical industry.
- (d) Managing a dedicated online portal for promoting the policy and processing investment applications.
- Enhancing Ease-of-Doing Business**      **6.**      This policy ensures ease of business and ensures conducive business environment in the state.
- 6.1 Time bound clearances:**
- Providing speedy and time bound clearances is one of the prime intentions of this policy. Towards this goal, the Government of Assam shall endeavour to provide timely delivery of services, clearances, approvals, permits, etc. through the Act. Procedural reforms will be undertaken to ensure that industry and investor requests are processed and approved within timeline as notified in relevant acts of the concerned department.
- 6.2 Any Bulk Drug Park or Medical Device Parks sanctioned under Central Government Scheme** shall be developed by the Industries, Commerce & PE Department. Incentives for units in such parks, which are other than those provided in this policy, shall be determined by the Department after due approval of the cabinet.
- Incentive Framework**      **7.**      **7.1 Fixed Capital Investment**
- (a) The cost of land and land development shall not be included in the Fixed Capital Investment calculation.
- (b) Refurbished or Relocated plant and machinery shall be allowed up to 40% of the FCI. This allowance shall be granted only to units evaluated by the Government of India for including refurbished or relocated plant and machinery.
- (c) The Eligible investment in building and civil construction as defined in existing Industrial and Investment Policy of Assam, 2019 shall be capped at 10% of the Fixed Capital Investment.
- (d) For remaining components, the definition of Eligible Fixed Capital Investment shall be as per existing Industrial and Investment Policy of Assam, 2019.
- (e) Any Payments made through cash shall be treated as ineligible amount for investment. Moreover, the payments that are reflecting in the bank statement of the industrial unit will only be considered for calculation of Fixed Capital Investment and incentives thereafter.
- (f) The investment made until date of Commencement of Commercial Production or Operations shall only be considered to deduce Eligible Fixed Capital Investment.

- (g) Subsidy shall be disbursed only to those units which are functional at the time of disbursement of the subsidy.

## 7.2 Category 1:

### **Private Pharmaceutical and Medical Device Parks**

#### **(a) Assistance on Capital Investment:**

This incentive shall be provided to develop common infrastructure and utilities in Private Pharmaceutical and Medical Devices Parks. This subsidy shall be limited to 30% of the investment value subject to a maximum limit of INR 15 Crores.

- (b) These incentives shall follow the following conditions, namely:—

- (i) The developed area of the park should be at least 15 acres.
- (ii) The industrial park should commence operations within the duration of the policy.
- (iii) The developer shall claim the incentives only after the commencement of operation and post 30% of the allocable area being allotted to Industries related to Pharmaceuticals and Medical Devices.
- (iv) The incentive shall be disbursed in 3 annual installments.
- (v) The following Project Components shall be eligible for consideration of incentive, namely:—
  - (a) Boundary Wall;
  - (b) Site Development;
  - (c) Internal Roads;
  - (d) Drainage and Sewerage System;
  - (e) Drawl of Power line and power distribution network within the industrial park;
  - (f) Entry or Exit and Security systems;
  - (g) Cold storage and warehouse;
  - (h) Common testing facilities;
  - (i) Environmental infrastructures such as Effluent treatment plant (ETP), Water treatment plant (WTP), Pollution control equipment;
  - (j) Bore well, water tank and internal pipeline network for water, electricity and gas;
  - (k) Common Storage/logistics facilities;

(l) Any other common utility facilities directly related to Pharmaceuticals and Medical Device industry;

(vi) The Industrial Park should have adequate green cover, open space and parking bay.

### 7.3 Category 2:

#### Manufacturing Units

##### (a) Special Assistance on Capital Investment:

Investment Range (FCI)	Incentive Details
Up to INR 50 crores	15% subsidy on Fixed Capital Investment Up to INR 7.5 crores to be disbursed in 3 annual instalments
Above INR 50 to 100 crores	15% subsidy on Fixed Capital Investment Up to INR 15 crores to be disbursed in 5 annual instalments
Above INR 100 crores	15% subsidy on Fixed Capital Investment Up to INR 150 crores. The Empowered Committee shall determine the no. of instalments of disbursement.

##### (b) Patent Assistance/ Intellectual Property Assistance:

50% reimbursement of expenses on patents, copyrights, trademarks and geographical indicators up to INR 40 lakh.

##### (c) Training Incentives:

One-time Overseas Training Subsidy of up to Rs. 50,000 per resident of Assam for start-up units bearing My Assam Start-up ID (MASI) may be provided for overseas training/skill upgradation in manufacturing, quality control, or leadership for up to 5 employees within 3 years from the date of commercial production.

### 7.4 Additional Incentives

In addition to above, a unit shall be eligible to avail incentives under existing Industrial and Investment Policy of Assam, 2019 or any other policies or schemes of Government of Assam, without duplicity of benefits.

7.5 These incentives are designed to complement Government of India initiatives and provide enhanced benefits to investors setting up operations in the state in the pharmaceutical sector.

**Governance 8. 8.1 Nodal Agency**

Government of Assam shall notify the Nodal Agency for effective implementation of the policy. This agency shall be responsible for the effective implementation of the policy, ensuring a conducive environment for the sustained growth of the pharmaceutical ecosystem in the state. It shall act as a Single Window for engagement with all ecosystem stakeholders, including investors, industry players and government bodies. The Nodal Agency may set up a dedicated Project Management Unit (PMU) staffed with professionals to support its operations.

**8.2 Empowered Committee (EC)**

<b>Sl. No.</b>	<b>Designation</b>	<b>Role</b>
1.	Hon'ble Minister, Industries, Commerce and Public Enterprises Department, Government of Assam	Chairperson
2.	Senior-most Secretary to Government of Assam, Finance Department or his/her representative not below the rank of Secretary	Member
3.	Senior most Secretary to the Government of Assam, Industries, Commerce & Public Enterprises department or his/her representative not below the rank of Secretary	Member
4.	Senior-most Secretary to Government of Assam, Revenue and Disaster Management department or his/her representative not below the rank of Secretary	Member
5.	Senior-most Secretary to Government of Assam, Power department or his/her representative not below the rank of Secretary.	
6.	Senior-most Secretary to Government of Assam, Health and Family Welfare department or his/her representative not below the rank of Secretary	Member

7.	Senior-most Secretary to Government of Assam, Labour Welfare department or his/her representative not below the rank of Secretary	
8.	Commissioner of Food & Drug Administration, Assam	Member
9.	Member Secretary, Pollution Control Board, Assam	Member
10.	Head of the Notified Nodal Agency	Member
11.	Any other official co-opted by the Chairperson	Member
12.	Secretary to the Government of Assam, Industries, Commerce & Public Enterprises department	Member Secretary

#### 8.2.1 Terms of Reference for the Empowered Committee:

- (i) The committee shall monitor the effective implementation of the policy and ensure inter departmental coordination for timely resolution of investor issues.
- (ii) At least five members including Chairperson, Member Secretary and Senior-most Secretary to Government of Assam or his representative not below the rank of Secretary from Finance, Health and Family Welfare shall be necessary for any sitting of the Empowered Committee (EC).
- (iii) The Empowered Committee shall oversee projects with Fixed Capital Investment of more than INR 100 crore, which will require approval from the state cabinet based on the Committee's recommendations.
- (iv) The chairperson may co-opt any official like Commissioner, Industries and Commerce, Assam, Managing Directors of State Industrial Corporations etc.
- (v) The Committee shall review implementation of various incentives in the State and may suggest remedial measures as and when felt necessary.

#### 8.3 Incentive Approval Process:

- (i) Eligibility Certificate and incentives under Industrial and Investment Policy Assam (IIPA), 2019 shall be considered separately as per existing Industrial and Investment Policy Assam, 2019.
- (ii) For incentives under Assam Pharmaceutical and Medical Device Policy 2025, State Level Committee defined as under shall be responsible for evaluation and grant of incentives.

Sl. No.	Designation	Role
1.	Senior most Secretary to the Government of Assam, Industries, Commerce & Public Enterprises department or his/her representative not below the rank of Secretary	Chairperson
2.	Secretary to Government of Assam, Finance Department or his/her representative	Member
3.	Secretary to Government of Assam, Revenue and Disaster Management department or his/her representative	Member
4.	Secretary to Government of Assam, Power department or his/her representative	Member
5.	Secretary to Government of Assam, Health and Family Welfare Technology department or his/her representative	Member
6.	Secretary to Government of Assam, Labour Welfare department or his/her representative	Member
7.	Member Secretary, Pollution Control Board, Assam	Member
8.	Commissioner, Industries and Commerce, Assam	Member
9.	Commissioner of Food & Drug Administration, Assam	Member
10.	Any other official co-opted by the Chairperson	Member
11.	Head of the Notified Nodal Agency	Member Secretary

### 8.3.1 Terms of Reference for the SLC:

- (1) The Committee shall be responsible for approval of the deserving applications w.r.t. all incentives (except those under existing Industrial and Investment Policy of Assam, 2019) under the policy.
- (2) The Committee shall meet as and when necessary, at least once in a quarter.

- (3) The Chairperson of the Committee(s) may co-opt any expert(s)/Officer (s) as and when necessary.
- (4) At least five members including Chairperson, Member Secretary, representatives of Finance and Information Technology department shall be necessary for any sitting of the State Level committee.
- (5) The State Level Committee shall monitor the smooth implementation of the policy and may suggest remedial measures to the Government of Assam as and when felt necessary.

#### **8.4 Interpretation:**

The decision of Industries, Commerce and Public Enterprises department, Government of Assam in regards to interpretation of any clause of the policy shall be final and binding.

#### **8.5 Rights of the State Government:**

- 8.5.1 Industries, Commerce and Public Enterprises Department, Government of Assam reserves the right to amend any provision(s) including amendment or withdraw any of the incentives or subsidies as and when necessary for development of industries and in the interest of the general people of the State from time to time under the provision of the Policy.
- 8.5.2 Industries, Commerce and Public Enterprises Department, Government of Assam reserves the right to review the matter regarding sanction or disbursement of subsidies or incentives to the eligible industrial unit(s) and in this connection, the State Government's decision shall be final and binding.
- 8.5.3 Industries, Commerce and Public Enterprises Department, Government of Assam, reserves the right to modify the eligible or non-eligible list of the industries as and when required in the interest of overall economic growth of the State and preservation of environment and ecology.
- 8.5.4 Industries, Commerce and Public Enterprises Department, Government of Assam, reserves the right to make or amend the necessary rules or guidelines for implementation of this policy as and when required.

#### **8.6 Guidelines for Implementation**

The Operational guidelines for implementation of the policy shall be issued separately by Industries, Commerce and Public Enterprises Department, Government of Assam.

**LAKSHMANAN S,**  
Secretary to the Government of Assam,  
Industries, Commerce and Public Enterprises Department.